

DEPARTMENT OF HEALTH & HUMAN SERVICES

John E. Klemmer, C.O. 3-12-97
Public Health Service
D1257B

CERTIFIED

RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260
FAX: 313-226-3076

WARNING LETTER
97-DT-07

March 12, 1997

Mr. Yossif Basit, Owner
Oriental Foods, Inc.
19384 John R.
Detroit, MI 48203

Re: FDA Sample # 3048460
Entry #: 5516945173-3
Product: Hulled Sesame Seeds

Dear Mr. Basit:

An inspection was made of your firm on January 30, 1997 by Investigator Barbara A. Moss. The inspection found that the referenced FDA sample, consisting of 50 lb. bags of hulled sesame seeds (50 pounds) that had been detained by our office on November 14, 1996, was distributed into commerce without a proper release from the Food and Drug Administration. Our inspection found that none of the product from this entry was available at your firm and you had no processing records which showed that the sesame seeds from this specific entry were processed into Tahini by your firm.

This is a violation of Title 21, Code of Federal Regulations, Part 1.90 (21 CFR 1.90), which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA. The U.S. Customs Service issued a Notice of Refusal of Admission and Notice of Redelivery (copy enclosed) on December 9, 1996 for the above referenced entry.

Failure to promptly correct this situation and prevent future distribution of entries prior to receipt of a May Proceed or Release Notice may result in regulatory action without further notice such as seizure, injunction, or detention without physical examination of future entries. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act and the regulations promulgated under the Act.

Please notify us in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct this violation and to prevent its recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which corrections will be made. Your response should be directed to this office to the attention of Mr. John E. Klemmer, Compliance Officer.

Sincerely yours,

John P. Klemmer
for Brenda J. Holman
District Director